Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Q&A: Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices

Questions and answers

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Do I still need to be able to demonstrate that the device(s) comply with the Australian essential principles for safety and performance?

Yes.

All devices supplied in Australia must comply with the Australian essential principles of safety and performance that are specified in the Therapeutic Goods (Medical Devices) Regulations 2002, including the labelling requirements. Compliance with the essential principles may be assessed through an application audit.

An application for inclusion will be selected for auditing if:

- The application is for a kind of medical device that is prescribed by regulation 5.3 of the medical devices regulations;
- There are concerns about the information provided in the application or about the device;
- There are signals or other information regarding the performance or safety device (or similar devices).

What happens if I submit an application for inclusion without the documents prescribed in Table 2 of the guidance for the relevant Class of medical device?

A legislative instrument provides that certain documents must accompany an application for inclusion. This instrument refers to Table 2 of the guidance, which details the specific documents required for each Class of medical device (including IVDs).

If you don't provide the relevant document(s) in your application, it will not pass preliminary assessment and will be refused.

For example, you have a Class IIb medical device and the linked Manufacturer Evidence for your application for inclusion is an MDSAP certificate, but:

- You did not attach any of the following documents to your application:
    - a 510(k) or De Novo Decision summary issued the US FDA, or
    - a Class III Heath Canada Medical Device Licence, or
    - a Japan pre-market approval certificate.

- In this case, you will be advised in writing that your Class IIb application did not pass preliminary assessment and was refused. The reasons for the refusal will be provided.

What happens if the documents I provide in my application for inclusion do not cover all of the devices of the kind in my application?

If the documents provided in your application (as linked Manufacturer Evidence and attachments to the application form) do not cover all of the devices of the kind in your application, the TGA may decide to impose conditions on the ARTG entry that limit that entry to only those devices for which the evidence of assessment in accordance with Table 2 has been provided. The conditions may also require you to notify the TGA and provide appropriate documentation if you decide to import and/or supply additional devices of that kind under that ARTG entry.

Multiple conformity assessment documents relating to product assessment (for example, multiple 510K summaries) can be used to support the range of medical devices intended to be supplied.

What will happen if I submit an application for inclusion in the ARTG of a Class III or AIMD device and provide a Premarket Approval (PMA) issued by the US FDA in my application? What level of application audit should I expect?

Any application for ARTG inclusion of a Class III or AIMD medical device that passes preliminary assessment, and for which a TGA-issued conformity assessment certificate is not in force, **must** be selected for an application audit.

Level of application audit

Our decision on the level of audit (Level 1 or 2) will be based on:

- information provided in your application, and/or

- information or signals that the TGA has regarding the device (or similar devices) (e.g. post-market signals from overseas regulators, claims about performance or clinical indications).

Level 2

The application will undergo a Level 2 audit if:

- the device in the application does not appear to be the same as the device specified in the PMA, including differences in the UPI, design, intended purpose or clinical indications, or
- there are other signals that raise safety or performance concerns.

We will request clinical evidence (and other evidence as required) that demonstrates compliance of the device with the essential principles in addition to the documentation required for a Level 1, as outlined below.

Level 1

If none of the criteria for Level 2 audits apply, the application will usually undergo a Level 1 audit, and we will request the following:

- labelling, instructions for use and other product information
- FDA report/supporting information for the PMA.

Note: In cases where the device appears to be different to the one specified in the PMA the TGA may request further information before proceeding with a level 2 audit. This information can include:

- *Product labels and IFU submitted to the overseas regulator*

- *Manufacturer generated submission to the overseas regulator (including, but not limited to, the CER)*
- *Manufacturer declaration*

In cases where this information demonstrates a clear link between the device and the assessment by the overseas regulator a Level 1 may be considered.

What will happen if I submit an application for inclusion in the ARTG of a Class IIb device and provide a MDSAP certificate and a 510(k) summary issued by the US FDA in my application? Will my application be selected for audit?

If the application for the Class IIb device passes preliminary assessment, and a TGA-issued conformity assessment certificate is not in force for the device, and the application is for:

- a barrier (other than a condom) indicated for contraception or prevention of the transmission of disease in the course of penile penetration during sexual intercourse, or
- an implantable contraceptive device, or
- a device specifically intended to be used for disinfecting another medical device, or
- an implantable intra-ocular lens, or
- or an intra-ocular visco-elastic fluid,

then it **must** be selected for audit.

Applications for any other device may be selected for audit if there are concerns about the information provided in the application or about the device, including:

- classification of the device not aligning with the intended purpose

- adverse event reports for the device or device family
- novel technology or novel use of an existing technology.

Level of application audit

The following will be given consideration when we decide on the level of audit (Level 1 or 2):

- information provided in your application, and/or
- information or signals that the TGA has regarding the device (or similar devices) (e.g. post-market signals from overseas regulators, claims about performance or clinical indications), and/or
- the category of device.

Level 2

Generally, applications for the following devices will undergo a Level 2 audit:

- implantable barrier contraceptives
- medical device disinfectant or sterilants (other than hardware)
- intra-ocular visco-elastic fluids
- implantable devices that are not sutures, staples, dental feelings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors
- other devices clinical and/or safety claims for which require verification.

We will request clinical evidence (or microbial efficacy reports, where relevant) that demonstrate compliance of the device with the essential principles, in addition to the Level 1 documentation.

Level 1

Generally, applications for the following devices will undergo a Level 1 audit:

- hardware intended for the disinfection or sterilisation of devices (e.g. steam steriliser)
- barrier contraceptives (other than male condom) that is not implantable
- posterior chamber implantable intra-ocular lens.

We will request the labelling, instructions for use and other product information, and the FDA report/supporting information for the 510(k) approval.

What will happen if I provide a MDSAP certificate in my application for inclusion of a Class Is device in the ARTG?

If the application passes preliminary assessment, the kind of device will most often be included in the ARTG without an application audit.

However, in cases where there are issues with the information provided in the application or concerns about the device, an application may be selected for audit.

Level of application audit

The level of application audit (Level 1 or 2) will be chosen based on the particular issues.

Level 2

If there are concerns with the safety or performance of the device, then a Level 2 audit will be undertaken.

We will request clinical evidence (or other information as required) that demonstrates compliance of the device with the essential principles, in addition to the documentation required for a Level 1 audit.

Level 1

Generally, a Level 1 audit will be undertaken where the concerns are limited to:

- classification, or
- GMDN, or
- manufacturer identity, or
- other information provided in the application (e.g. intended purpose statement or answers to questions about the characteristics of the device)

We will request the labelling, instructions for use and other product information.

MDSAP certificates

The TGA has access to MDSAP assessment reports but may request information from the sponsor if further clarification around the certificate scope and/or manufacturer is required.

What will happen if I provide a MDSAP certificate and a 510(k) summary issued by the US FDA in my application for inclusion of a Class 3 IVD in the ARTG?

If the application passes preliminary assessment, and a TGA-issued conformity assessment certificate is not in force for the device, it **must** be selected for an application audit (technical file review) if it includes any of the following IVDs:

- an IVD that is intended for self-testing, or
- an IVD that is intended for point of care testing, or
- an IVD that is intended for detecting the presence of, or exposure to, a sexually transmitted agent, or
- an IVD for managing and monitoring the treatment of infections diagnosed using a Class 4 IVD medical device (for example, quantitative nucleic acid test (NAT) and genotyping assays for HIV and HCV), or
- an IVD that is intended to be supplied for use under the pharmaceutical benefit scheme, or
- an IVD that is intended to be supplied for use in a national screening program.

Applications for Class 3 IVDs that include devices other than those listed above may also be selected for audit if there are concerns about information provided in the application, or about the device and its intended purpose.

Can I use an MDSAP certificate with my ARTG inclusion application for an IVD medical device?

A Medical Device Single Audit Program (MDSAP) certificate is now one of the *conformity assessment documents* (covering the manufacturer's quality management system) that you can provide when submitting your application for inclusion for a kind of IVD medical device in the ARTG.

As usual, you will be required to submit a new Manufacturer Evidence application for the MDSAP certificate and wait for acceptance, prior to submitting an application for ARTG inclusion for your IVD medical device.

What should I do if my MDSAP certificate covers non-IVD and IVD medical devices?

If your MDSAP Certificate covers both non-IVD medical devices and IVD medical devices, you will need to submit two separate applications for Manufacturer Evidence: one Manufacturer Evidence ID will be used for your non-IVD medical device applications, and the other Manufacturer Evidence ID will be used for your IVD medical device applications.

What if I have multiple certificates for IVD medical devices of the same kind?

Sometimes a single certificate is not adequate to cover all the IVD medical devices captured under a single ARTG inclusion application (even though these devices are all *of the same kind*). In these situations, the ARTG inclusion application form for IVD medical devices allows sponsors to choose multiple Manufacturer Evidence IDs for a single ARTG inclusion application.

You will need to have each of your *conformity assessment documents* (covering the manufacturer's quality management system) submitted and accepted under individual Manufacturer Evidence IDs. Then, when you fill in the information in your ARTG inclusion application, you should select all the Manufacturer Evidence IDs relevant to the IVD medical devices captured under your ARTG inclusion application.

For an existing ARTG entry for an IVD medical device how do I replace a CMDCAS or IAF ISO 13485 certificate with an MDSAP certificate?

If, due to the recent legislative changes, you need to replace an existing manufacturer's CMDCAS or IAF ISO 13485* certificate linked to an existing ARTG entry for an IVD medical device with a new MDSAP certificate you will first need to submit a Manufacturer Evidence application for the new MDSAP certificate (following the standard process for submission of new Manufacturer Evidence).

After your Manufacturer Evidence application is accepted, you should contact the TGA and request re-linking of your new Manufacturer Evidence ID with your existing ARTG entry. To do this, please send an 'MDSAP certificate relinking' request to the TGA via email to devices@tga.gov.au. In your email please include the following:

- State in the subject line of your email: '[Insert Sponsor Name] - Replacement of CMDCAS or IAF ISO 13485 with MDSAP certificate'; and
- provide a brief description of your request with the reasons; and
- include a table of ARTG entries with their current Manufacturer Evidence ID numbers (include certificate details: CMDCAS or IAF ISO 13485). In the table also provide your new Manufacturer Evidence ID numbers for your MDSAP certificates that need to be linked to your individual ARTG entries.

IMPORTANT: Please note that this 'MDSAP certificate relinking' email process only applies to requests for replacement of a CMDCAS or IAF ISO 13485 certificate with a new MDSAP certificate for existing ARTG entries for IVD medical devices.

* An IAF ISO 13485 certificate means certificate issued by a certification body that is accredited by a signatory member of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MRA).

If you require a variation of any other information entered on your existing ARTG entries, or addition of any new IVD medical devices, you are required to follow standard procedure and submit a Device Change Request or IVD Variation Application (whatever is relevant) to the TGA, and pay the respective fee.

Please refer to the Varying entries in the ARTG - medical devices and IVDs guidance document for more information.